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August 21, 2025

Honorable Rebecca R. Pallmeyer
U.S. District Court for the Northern District of
Illinois,
Eastern Division
Everett McKinley Dirksen United States Courthouse
219 South Dearborn Street
Chicago, IL 60604

**Re: Order Excluding Defendant Abbott Laboratories' Expert Witness, Dr.
Robert Makuch, Subject to Supplementation of Expert Report**

Judge Pallmeyer:

Abbott writes to seek guidance on the issues the Court raised in its August 15, 2025 order regarding Abbott's expert biostatistician, Dr. Robert Makuch. *See* Master Dkt. 683 at 31–32, 60.

First, the Court explained that while Dr. Makuch's report cited "a report prepared by Dr. Martin asserting that RaiLee Mar's diet exceeded 75% human milk," it "provides no mention of D.B.'s feeding regimen that explains why the 75% threshold is applicable to his case." *Id.* at 32. There is an explanation for this: Dr. Makuch issued separate reports in the *Mar* and *Etienne* cases. Those reports are identical except for a footnote that explained the basis for applying the 75% threshold to each infant. Footnote 17 of Dr. Makuch's *Etienne* report discusses the undisputed fact that D.B.'s feeding regimen exceeded the 75% threshold:

I rely on the amount of human milk fed to the infant in this case for the clinical relevance of studies in which infants in each study group received at least 75% of their enteral feeds on average as human milk. I understand that human milk comprised over 75% of the plaintiff's enteral feeds prior to NEC in this case. [Expert Report of Dr. Elizabeth Flanigan (*Etienne*) at 14; Expert Report of Dr. Brian Smith (*Etienne*).]

Ex. A (*Etienne* Makuch Rep.) ¶ 28 & n.17.

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Abbott suspects that the Court was not aware that Dr. Makuch filed an *Etienne*-specific report, because neither party attached it to their briefs. Plaintiffs attached the *Mar* report but not the *Etienne* report, presumably because none of their arguments turned on footnote 17. And Abbott didn't attach the *Etienne* report either because it wasn't relevant to addressing Plaintiffs' motion. Abbott submits that report here (Ex. A), in the hope that it will resolve the Court's concern.

D.B.'s feeding ratio is, in fact, undisputed. Plaintiffs' expert Dr. Flanigan calculated the amounts as 8,440.4 mL of human milk (about 90%) and 873 mL of Abbott's formula (about 10%). Ex. B (*Etienne* Flanigan Rep.) at 14. Abbott's expert Dr. Smith agreed that Dr. Flanigan's calculation "appears accurate and would mean that 9% of [D.B.'s] feeding volume was" Abbott formula. Ex. C (*Etienne* Smith Am. Rep.) at 12.

Dr. Makuch testified about all of this at his deposition. Master Dkt. 627-10 (Makuch Dep.) at 38:17–39:5, 221:25–226:23. And in its March 14, 2025 Omnibus Opposition to Plaintiffs' Motions to Exclude, Master Dkt. 626—without contradiction from Plaintiffs—Abbott stated that "the undisputed evidence shows that each infant was fed more than 75% human milk: in *Mar*, [R.M.] received ~95% of her nutrition from human milk, and in *Brown/Etienne*, [D.B.] received ~91%." *Id.* at 7.

Second, the Court also discussed what it described as the "strenuously debated" issue regarding the "proper way to measure an infant's exposure" to formula and noted that Dr. Makuch's "voice" was "missing" on that issue. Master Dkt. 683 at 31. There is a straightforward explanation for that too: Dr. Makuch was responding to Plaintiffs' experts, and those experts never suggested it was appropriate to measure an infant's formula exposure based on either "the days prior to the onset of NEC" (Master Dkt. 683 at 31) or, as a potentially conflicting alternative, "beginning at their first exposure to formula" (*Mar* Dkt. 96 at 6). Plaintiffs' argument along these lines is an after-the-fact attorney invention, which was never mentioned in their expert reports nor in their experts' depositions, much less in the scientific literature.

In other words, Dr. Makuch had no reason to address an issue that none of the Plaintiffs' experts ever raised. In any event, he is a biostatistician. For a meta-analysis, he takes the studies as they are. To determine the proportion of human milk, he simply relied on how the study itself "reported" the data and otherwise estimated "the amount based on information reported in the publication." Ex. A (*Etienne* Makuch Rep.) ¶ 27. Plaintiffs have not identified one study in Dr. Makuch's analysis that measures exposure the way their counsel has proposed.

On the contrary, Plaintiffs' own epidemiologist Dr. Spector acknowledged that his causation opinion "depend[ed] on the percentage of diet that is made of formula" (*Etienne* Dkt. 60, Ex. 3, 12/23/24 Spector Dep. at 286:19–22) and then specifically limited his opinion to diets that were "predominantly" formula, unlike D.B.'s. *Id.*, Ex. 1, Spector Report at 9, 15, 18, 19. As explained more fully in Abbott's Motion to Exclude Dr. Spector and Dr. Flanigan (*Etienne* Dkt.

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60), Dr. Spector has never stated or even implied that what he *really* meant was “predominantly” formula in “the days prior to the onset of NEC” or following the “first exposure to formula.” Indeed, every one of Dr. Spector’s studies that reported feeding ratios used measurements from birth (or shortly thereafter)—not from the first formula feeding or in the days before NEC. *See Id.* at 9-10.

Abbott’s expert neonatologist, Dr. Camilia Martin, explained why measuring feeding ratios from birth makes sense. She explained—without contradiction from Plaintiffs’ experts—that human milk “modif[ies] the function of the gastrointestinal tract and the immune system” in lasting ways, including by creating “mature immune function” and “mature barrier defenses.” Ex. D (*Etienne* Martin Am. Rep.) at 30. Thus, she testified, the level of protection is “all about the proportion of your *total* intake.” Dkt. 627-13 (excerpt of *Diggs* Martin Dep.) at 83:19–20. This has been long understood in the NICU community as confirmed, for instance, by a prominent 2009 study finding that “[t]he likelihood of NEC or death after 14 days [of life] was decreased . . . for each 10% increase in the *proportion of total intake* as HM [human milk]” from the infant’s very first feedings. *Etienne* Dkt. 60 at Ex. 28 at 1. Those lasting protections would be ignored entirely if an infant’s diet were not measured until the days before NEC.

Abbott hopes that this additional information sufficiently addresses the issues raised in the Court’s August 15, 2015 order, but will, of course, submit a supplemental expert report if the Court believes doing so would still be helpful.

Sincerely,



James F. Hurst, P.C.